

REMARKS

This responds to the Final Office Action dated December 11, 2009.

No claim is amended. Claims 1-10, 12-14, 73-79, 81, 83, and 84 remain pending in this application.

The Rejection of Claims Under § 103

Claims 1-10, 12-14, 73-79, 81, 83 and 84 are rejected under 35 U.S.C. §103(a) as being unpatentable over Dennis et al. (U.S. Patent No. 6,114,164, hereinafter “Dennis”) in view of Kofidis et al. (*Journal of Thoracic and Cardio. Surg.*, hereinafter “Kofidis”), Farb et al. (U.S. Patent No. 6,048,722, hereinafter “Farb”), Bursac et al. (*Am. J. Physiol.* 277, hereinafter “Bursac”) and Terracio et al. (*In Vitro Cell. And Develop Bio.*, hereinafter “Terracio”).

Claim 1

Applicant respectfully traverses the rejection and submits that for at least reasons discussed below, the Office Action does not set forth a proper *prima facie* case of obviousness.

A) The Office Action Does Not Provide a Proper Reason to Address the Deficiency of the Cited References.

Applicant respectfully submits that the cited portions of Dennis, Kofidis, Farb, Bursac, and Terracio, individually or in combination with each other and reasoning given in the Office Action, do not provide the claimed subject matter. For example, Applicant is unable to find in the cited portions of Dennis, Kofidis, Farb, Bursac, and Terracio, individually or in combination, among other things, one or more biological stimulus agents selected from protein and nucleic acid, and a biological treatment administration module including the one or more biological stimulus agents, as recited in claim 1.

Applicant is also unable to find in the Office Action a proper reason that addresses this deficiency of the cited references. The Office Action cites various cases to support an assertion that “positive recitation in the claims that the apparatus includes a protein or nucleic acid agent

does not further patentably distinguish the structure of the claim”. As discussed below, the cited cases do not support this assertion.

Ex parte Thibault

The Office Action asserts, in paragraph 4, on page 5:

Note positive recitation in the claims that the apparatus includes a protein or nucleic acid agent does not further patentably distinguish the structure of the claim because “Expressions relating the apparatus to contents thereof during an intended operation are of no significance in determining patentability of the apparatus claim.” *Ex parte Thibault*, 164 USPQ 666, 667 (Bd. App. 1969). See MPEP 2115.

However, the line of cases cited in MPEP § 2115, including *Ex parte Thibault*, “is limited to claims directed to machinery which works upon an article or material in its intended use.” MPEP § 2115. The claimed apparatus does not “work upon” the one or more biological stimulus agents selected from protein and nucleic acid as recited in claim 1. Instead, the cells constitute the article or material worked upon by the claimed apparatus, while the one or more biological stimulus agents are part of the claimed apparatus. Therefore, *Ex parte Thibault* and MPEP § 2115 do not support the rejection.

Ex parte Masham, In re Yanush, In re Finsterwalder, and In re Casey

The Office Action further asserts, in Response to Arguments (paragraph 5), on page 8:

... it is fundamental that an apparatus claim defines the structure of the invention and not how the structure is used in a process, or what materials the structure houses in carrying out the process. *Ex parte* (sic) *Masham*, 2 USPQ2d 1647, 1648 (BPAI 1987). See also *In re Yanush*, 477 F.2d 958, 959, 177 USPQ 705, 706 (CCPA 1973); *In re Finsterwalder*, 436 F.2d 1028, 1032, 168 USPQ 530, 534 (CCPA 1971); *In re Casey*, 370 F.2d 576, 580, 152 USPQ 235, 238 (CCPA 1967).

Ex parte Masham holds that “the recitation of ‘completely submerged in the developer material’ does not impose any structural limitations upon the claimed apparatus”. See also MPEP § 2115. *In re Yanush* holds that “[w]hether a vibrator is operated gently to settle materials in a mold or more forcefully to “hammer” them is a process limitation which does not limit or define the claimed apparatus.” *In re Finsterwalder* holds that “the fact that appellant discloses the apparatus as advantageous in the ‘free cantilever’ method of construction will not save the claims if the apparatus defined thereby would have been obvious to a person of ordinary skill in the bridge-construction art intending to use it in a somewhat different construction method.” *In re*

Casey holds that “[p]resenting adhesive tape to a roll in such a way as to adhere it to the roll and causing movement of the roll ‘while adhesive tape is adhered to said surface’ are method steps and cannot properly confer patentability on an apparatus claim.” Thus, *Ex parte Masham*, *In re Yanush*, *In re Finsterwalder*, and *In re Casey* are all related to how a claimed structure is intended to be used. In contrast, the one or more biological stimulus agents recited in claim 1 are part of the claimed apparatus, rather than the intended use of the claimed apparatus. The intended use of the claimed apparatus is to provide *in vitro* conditioning of cells prior to a cell therapy administered into a body having a myocardium, as recited in the preamble of claim 1, rather than housing the one or more biological stimulus agents.

Additionally, it is unclear how any of *Ex parte Masham*, *In re Yanush*, *In re Finsterwalder*, and *In re Casey* would support the assertion that “it is fundamental that an apparatus claim defines the structure of the invention and not ... what materials the structure houses in carrying out the process.” Applicant respectfully requests a clarification showing what in any of these cases supports this assertion, or withdrawal of the rejection.

In re Hughes

The Office Action further asserts, under Response to Arguments (paragraph 5) on page 9:

Applicants are also encouraged to consider *In re Hughes* (9 USPQ 223) which involves an apparatus and the material used therewith. The device in *In re Hughes* applies a material to a web of paper. Neither the material (dye) used with the apparatus nor the material worked on (paper) added structure to the device to patentably distinguish the apparatus over the prior art which did not teach the claimed dye. In the instant application, the biological stimulus agent would be equivalent to the dye in *In re Hughes* and therefore does not patentably distinguish the instant claims over the prior art rejections of record.

However, the alleged “material (dye)” in *In re Hughes* appears to be recited as a material worked upon by the printing device, rather than positively recited as a structural limitation. *In re Hughes* states:

We have held in *In re Smith*, 17 C.C.P.A. 644, 36 F.2d 302, that a person may not patent a combination of a device and the material upon which the device works, nor limit other persons from the use of similar material by claiming a device patent. If the material which appellant uses here for printing is new to the art, then such material may be patentable, but he may not take advantage of this in applying for a patent upon a mechanism to apply it. Any feature of the mechanism which is particularly constructed for the use of such a fluid might be patentable in combination or otherwise. Appellant can not, however, properly claim a combination of device and material worked upon. (emphasis added)

Thus, the holdings of *In re Hughes* apply to “a combination of device and material worked upon.” As discussed above, the one or more biological stimulus agents are not recited as a material worked upon by the claimed apparatus. Additionally, claim 1 would not “limit other persons from the use of similar material” (unless as part of the apparatus as claimed). Further, the apparatus of claim 1 has a feature that is constructed for the use of the one or more biological stimulus agents, i.e., the biological treatment administration module. Therefore, *In re Hughes* does not support the rejection.

B) The Office Action Does Not Provide a Proper Reason for the Combination of the Cited References.

Applicant also respectfully submits that the Office Action does not provide a proper reason for the combination of Dennis, Kofidis, Farb, Bursac, and Terracio. “[R]ejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.” *KSR Int’l Co. v. Teleflex Inc.*, 127 S.Ct. 1727, 1741, 82 USPQ2d 1385, 1396 (2007). The Office Action further asserts, under Response to Arguments (paragraph 5) on page 10:

The examiner is of the position that in view of these teachings, it would of have been obvious to one of ordinary skill in the art to modify the device of the primary reference to include a biological treatment administration module for the known and expected result of allowing any cells cultured in the device of the primary reference to be additionally chemically stimulated as suggested by the reference of Kofidis et al. while allowing the automation of all the stimulation structures and detection devices.

However, “to be additionally chemically stimulated” merely states what the modified device would do, rather than a reason for the modification (i.e., a reason for adding chemical stimulation to electrical and mechanical stimulations). The Office Action states, under Response to Arguments (paragraph 5) on pages 10-11:

“[I]t can be important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does.” *KSR*, 550 U.S. at ___, 82 USPQ2d at 1396. If any of these findings cannot be made, then this rationale cannot be used to support a conclusion that the claim would have been obvious to one of ordinary skill in the art.

However, Applicant is unable to find in the Office Action such “reason that would have prompted a person of ordinary skill in the relevant field to combine the elements”.

The Office Action states, under Response to Arguments (paragraph 5) on pages 10:

It is noted the rationale to support a conclusion that the claim would have been obvious is that all the claimed elements were known in the prior art and one skilled in the art could have combined the elements as claimed by known methods with no change in their respective functions, and the combination yielded nothing more than predictable results to one of ordinary skill in the art. KSR, 550 U.S. at ___, 82 USPQ2d at 1395; Sakraida v. AG Pro, Inc., 425 U.S. 273, 282, 189 USPQ 449, 453 (1976); Anderson 's-Black Rock, Inc. v. Pavement Salvage Co., 396 U.S. 57, 62-63, 163 USPQ 673, 675 (1969); Great Atlantic & P. Tea Co. v. Supermarket Equipment Corp., 340 U.S. 147, 152, 87 USPQ 303, 306 (1950).

However, Applicant is unable to find in the Office Action why “the combination yielded nothing more than predictable results to one of ordinary skill in the art”. For example, given that the alleged electrical stimulator and stress simulator of Dennis and the alleged biological treatment administration modules of Kofidis each have effects in changing properties of cells, Applicant is unable to find in the cited references and the Office Action what the overall effects on the cells would be and why such overall effects are “nothing more than predictable results”.

Therefore, Applicant respectfully traverses the assertion of obviousness as a conclusory statement without support of proper reasoning, and submits that the Office Action does not provide clearly articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.

Applicant respectfully requests reconsideration and allowance of claim 1.

Claims 2-10, 12-14, 73-79, and 81-84

Applicant respectfully traverses the rejection. Claims 2-10, 12-14, 73-79, 81, and 83-84 are dependent on claim 1, which is believed to be patentable for at least the reasons set forth above. Therefore, the discussion above for claim 1 is incorporated herein to support the patentability of claims 2-10, 12-14, 73-79, 81, and 83-84.

Applicant respectfully requests reconsideration and allowance of claims 2-10, 12-14, 73-79, 81, and 83-84.

CONCLUSION

Applicant respectfully submits that the claims are in condition for allowance, and notification to that effect is earnestly requested. The Examiner is invited to telephone Applicant's representative at (612) 373-6965 to facilitate prosecution of this application.

If necessary, please charge any additional fees or deficiencies, or credit any overpayments to Deposit Account No. 19-0743.

Respectfully submitted,

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CERTIFICATE UNDER 37 CFR 1.8: The undersigned hereby certifies that this correspondence is being filed using the USPTO's electronic filing system EFS-Web, and is addressed to: Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on this 10th day of March, 2010.

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Name

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